



DATE: November 29, 2007 SHEET 1\_ of 4\_

## Form PTO - 1449 (Modified)

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE  
(Modified) PATENT AND TRADEMARK OFFICEINFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

(Use several sheets if necessary)

ATTY. DOCKET NO.

6488.US.02

SERIAL NO.

09/709,829

APPLICANT

James J. Fort, *et al.*

FILING DATE

November 10, 2000

GROUP

1654

(37 CFR 1.98 (b))

## U.S. PATENT DOCUMENTS

EXAM. INITIAL			PATENT NUMBER	ISSUE DATE	PATENTEE	CLASS	SUB CLASS	FILING DATE
		A1	4,769,235	09/06/1988	Panoz, <i>et al.</i>			
		A2	4,904,699	02/27/1990	Bauer			
		A3	5,525,628	08/13/1996	Deboeck, <i>et al.</i>			
		A4	5,541,206	07/30/1996	Kempf, <i>et al.</i>			
		A5	5,648,497	07/15/1997	Kempf, <i>et al.</i>			
		A6	5,741,519	04/21/1998	Rosenberg, <i>et al.</i>			
		A7	5,773,025	06/30/1998	Baichwal			
		A8	5,889,051	03/30/1999	Chen, <i>et al.</i>			
		A9	5,914,332	06/22/1999	Sham, <i>et al.</i>			
		A10	5,939,099	08/17/1999	Grabowski, <i>et al.</i>			
		A11	5,948,426	09/07/1999	Al-Razzak, <i>et al.</i>			
		A12	6,027,747	02/22/2000	Terracol, <i>et al.</i>			
		A13	6,294,192	09/25/2001	Patel, <i>et al.</i>			
		A14	6,383,471	05/07/2002	Chen, <i>et al.</i>			
		A15	6,451,339	09/17/2002	Patel, <i>et al.</i>			
		A16	6,462,093	10/08/2002	Miyamoto, <i>et al.</i>			
		A17	6,608,198	08/19/2003	Dickman, <i>et al.</i>			
		A18	6,692,767	02/17/2004	Burnside, <i>et al.</i>			
		A19	6,730,319	05/04/2004	Maeder, <i>et al.</i>			
		A20	6,733,781	05/11/2004	Abu-Izza, <i>et al.</i>			
		A21	6,834,310	12/21/2004	Munger, <i>et al.</i>			
		A22	7,014,810	03/21/2006	Krull, <i>et al.</i>			
		A23	7,148,359	12/12/2006	Chemburkar, <i>et al.</i>			
		A24	7,229,641	06/12/2007	Cherukuri			

## U.S. PATENT APPLICATION DOCUMENTS

EXAM. INITIAL			PATENT NUMBER	PUB. DATE	PATENTEE	CLASS	SUB CLASS	FILING DATE
		A25	2002/0006443	01/17/2002	Curatolo, <i>et al.</i>			
		A26	2003/0054038	03/20/2003	Crew, <i>et al.</i>			
		A27	2005/0048112	03/03/2005	Breitenbach, <i>et al.</i>			
		A28	2005/0084529	04/21/2005	Rosenberg, <i>et al.</i>			
		A29	2005/0143404	06/30/2005	Rosenberg, <i>et al.</i>			

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## FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

EXAM. INITIAL		DOCUMENT NUMBER	PUBLI- CATION DATE	COUNTRY OR PATENT OFFICE	CLASS	SUB CLASS	TRANSLATION	
							YES	NO
	B1	2 343 234	16.03.2000	CA				
	B2	2 352 874	08.06.2000	CA				
	B3	2 367 020	21.09.2000	CA				
	B4	2 368 625	05.10.2000	CA				
	B5	2 374 931	11.01.2001	CA				
	B6	2 479 749	02.10.2003	CA				
	B7	2,501,245	22.04.2004	CA				
	B8	2 568 378	08.12.2005	CA				
	B9	0 414 422	27.02.1991	EP				
	B10	0 732 923	12.12.2001	EP				
	B11	0 852 140	03.12.2003	EP				
	B12	0 864 324	16.09.1998	EP				
	B13	0 864 326	16.09.1998	EP				
	B14	0 942 721	22.01.2003	EP				
	B15	0 988 106	29.03.2000	EP				
	B16	2 053 681	11.02.1981	GB				
	B17	90/06115	14.06.1990	WO				X
	B18	95/22319	24.08.1995	WO				
	B19	95/07696	23.03.1995	WO				
	B20	95/09614	13.04.1995	WO				
	B21	97/06781	27.02.1997	WO				X
	B22	97/46222	11.12.1997	WO				
	B23	98/22106	28.05.1998	WO				
	B24	98/24430	11.06.1998	WO				
	B25	00/57854	04.10.2000	WO				
	B26	00/74677	14.12.2000	WO				
	B27	01/00175	04.01.2001	WO				
	B28	01/22938	05.04.2001	WO				
	B29	01/23362	05.04.2001	WO				
	B30	01/34118	17.05.2001	WO				
	B31	01/34119	17.05/2001	WO				
	B32	01/52821	26.07.2001	WO				
	B33	01/91727	06.12.2001	WO				
	B34	02/20057	14.03.2002	WO				
	B35	02/096395	05.12.2002	WO				

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT  (Use several sheets if necessary)	APPLICANT <b>James J. Fort, et al.</b>	
	FILING DATE <b>November 10, 2000</b>	GROUP <b>1654</b>

(37 CFR 1.98 (b))

## FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

	B36	02/092595	21.11.2002	WO				
	B37	03/080120	02.10.2003	WO				
	B38	2004/039349	13.05.2004	WO				
	B39	2004/050068	17.06.2004	WO				
	B40	2004/054568	01.07.2004	WO				
	B41	2005/004836	20.01.2005	WO				
	B42	2005/007139	27.01.2005	WO				

## OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

EXAM. INITIAL			
	C1		Aungst, B.J., et al., "Improved Oral Bioavailability of an HIV Protease Inhibitor Using Gelucire 44/14 and Labrasol Vehicles", <i>B.T. Gattefosse</i> , <b>87</b> :49-54 (1994)
	C2		Awni, W., et al., "Significantly Reduced Food Effect and Pharmacokinetic Variability with a Novel Lopinavir/Ritonavir Tablet Formulation", <i>third IAS Conf. On HIV Pathogenesis and Treatment</i> , (2005)
	C3		BASF Fine Chemicals, "ExAct Excipients & Actives for Pharma", BASF, <b>2</b> :1-16 (1999)
	C4		Bouma, M.G., et al., "Novel Therapeutic Delivery Systems", <i>J. of Contr. Rel.</i> , <b>87</b> :199-308 (2003)
	C5		Breitenbach, J., "Melt Extrusion Can Bring New Benefits to HIV Therapy: The Example of Kaletra (R) Tablets", <i>Amer. J. of Drug Deliv.</i> , <b>4(2)</b> :61-64 (2006)
	C6		Breitenbach, J., "Melt extrusion: from process to drug delivery technology", <i>Eur. J. of Pharm. &amp; Biopharm.</i> , <b>54</b> :107-117 (2002)
	C7		Chiou, W.L. & Riegelman, S., "Pharmaceutical Applications of Solid Dispersion Systems", <i>J. of Pharm. Sci.</i> , <b>60(9)</b> :1281-1301 (1971)
	C8		Corrigan, I.I. & Healy, A.M., "Surfactants in Pharmaceutical Products and Systems", <i>Encycl. Of Pharm. Tech.</i> , 2639-2653 (2002)
	C9		Ford, J.L., "The Current Status of Solid Dispersions", <i>Pharm. Acta Helv.</i> , <b>61(3)</b> :69-88 (1986)
	C10		Forster, A., et al., "Selection of excipients for melt extrusion with two poorly water-soluble drugs by solubility parameter calculation and thermal analysis", <i>Intn'l J. of Pharm.</i> , <b>226</b> :147-161 (2001)
	C11		Hulsmann, S., et al., "Melt extrusion - an alternative method for enhancing the dissolution rate of 17 $\beta$ -estradiol hemihydrate", <i>Eur. J. of Pharm. &amp; Biopharm.</i> , <b>49</b> :237-242 (2000)
	C12		International Search Report & Written Opinion from PCT/US2004/027401 dated May 8, 2006
	C13		Karanth, H., et al., "Industrially Feasible Alternative Approaches in the Manufacture of Solid Dispersions: A Technical Report", <i>AAPS PharmSciTech</i> , <b>7(4)</b> :Art. 87 (2006)
	C14		Law, D., et al., "Physicochemical Considerations in the Preparation of Amorphous Ritonavir-Poly(ethylene glycol) 8000 Solid Dispersions", <i>J. of Pharm. Sci.</i> , <b>90(8)</b> :1015-1025 (2001)

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	<b>APPLICANT</b> <b>James J. Fort, et al.</b>	
	<b>FILING DATE</b> <b>November 10, 2000</b>	<b>GROUP</b> <b>1654</b>

**OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)**

EXAM. INITIAL		
	C15	Law, D., <i>et al.</i> , "Ritonavir-PEG 8000 Amorphous Solid Dispersions: <i>In Vitro</i> and <i>In Vivo</i> Evaluations", <i>J. of Pharm. Sci.</i> , <b>93(3)</b> :563-570 (2004)
	C16	Palmieri, G.F., <i>et al.</i> , "Characterization and dissolution studies of PEG 4000/fenofibrate solid dispersions", <i>S.T.P. Pharma Sci.</i> , <b>6(3)</b> :188-194 (1996)
	C17	Physicians Desk Reference, online excerpt, PDR Electronic Library
	C18	Physicians Desk Reference, online ... Norvir, Fenofibrate, and Greiseosulvin
	C19	Serajuddin, A.T.M., "Solid Dispersion of Poorly Water-Soluble Drugs: Early Promises, Subsequent Problems and Recent Breakthroughs", <i>J. of Pharm. Sci.</i> , <b>88(10)</b> :1058-1066 (1999)
	C20	U.S. Patent Application 09/438,994, James J. Fort, <i>et al.</i> , filed November 12, 1999
	C21	U.S. Patent Application 11/691,819, James J. Fort, <i>et al.</i> , filed March 27, 2007
	C22	U.S. Patent Application 11/773,185 Joerge Rosenberg, <i>et al.</i> , filed July 3, 2007
	C23	Zhu, T., <i>et al.</i> , "New Tablet Formulation of Lopinavir/Ritonavir is Bioequivalent to the Capsule at a Dose of 800/200 mg", <i>48<sup>th</sup> Int. Conf. On Antimic. Agents &amp; Chem., (ICAAC)</i> , (2005)

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